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November 10,1998

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" Street SW
Washington, DC 20204

## Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following phrase and statement:

## **Promotes Relaxation**

Valerian root extract may slow the central nervous system activity. Valerian has traditionally been used to help support restful sleep.

on the following product:

Tree of Life® Valerian

Very truly yours,

**Leiner Health Products** 

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs
William Cochran, Manager of Regulatory Affairs

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